*SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5561–5580*

*Adulteration*, Section 501(a)(1), the article consisted in part of a filthy substance; Section 501(a)(2), the article had been prepared under insanitary conditions; Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

*Misbranding*, Section 502(a), the labeling of the article was false and misleading; Section 502(b)(2), the article was in package form, and it failed to bear a label containing an accurate statement of the quantity of contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 503(b)(1), the article was dispensed without a prescription from a practitioner licensed by law to administer the article; Section 503(b)(4), the article was subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

## VIOLATIVE SALES OF PRESCRIPTION DRUGS

**5561. Various drugs.** (F.D.C. No. 40603. S. Nos. 41–889/91 M, 55–785 M, 55–787/9 M, 55–791 M, 84–801 M.)

INDICTMENT FILED: 1–14–58, E. Dist. Ky., against John Byron Miller, t/a J. B. Miller, pharmacist, Williamstown, Ky.

CHARGE: Between 6–1–57 and 6–12–57, *penicillin tablets* were dispensed three times and *cortisone acetate tablets* were dispensed twice without a prescription, which acts of dispensing were caused to be done by the defendant while the tablets were being held for sale after shipment in interstate commerce and which resulted in the tablets being misbranded under 503(b)(1).

In addition, various articles, namely, a number of *pink tablets* and *mephenesin tablets* and quantities of a *yellow oil* and a *liquid medicine* were caused to be introduced into interstate commerce by the defendant at Williamstown, Ky., for delivery to Albany, N.Y., and Nashville, Tenn., between the latter part of 1956 and 7–15–57. The articles were misbranded as follows:

502(b)(2)—the labels of the articles bore no statement of the quantity of contents.

502(e)(1)—the labels of the articles failed to bear the common or usual names of the articles.

502(e)(2)—the articles, other than the *yellow oil*, were fabricated from two or more ingredients, and the labels failed to bear the common or usual name of each active ingredient.

502(f)(1)—the labeling of the articles failed to bear adequate directions for use since the labeling failed to state the conditions and purposes for which the articles were intended.

503(b)(1)—the *mephenesin tablets* were dispensed without a prescription.

PLEA: Guilty.

DISPOSITION: 4–21–58. Sentence of 90 days in jail and fine of $2,250.

## DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

**5562. Del-Caps.** (F.D.C. No. 41316. S. Nos. 70–416/8 M.)

QUANTITY: 1 drum containing 24,850 capsules, 1 drum containing 49,850 capsules, and 1 drum containing 20,300 capsules at Philadelphia, Pa.

SHIPPED: 7–3–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: (24,850-capsule lot) "Lot No. 2881 * * * Formula Del-Caps 10 Mg."; (49,850-capsule lot) "Del-Caps 15 Timed Disintegration Capsule * * * Each Capsule Contains: Dextro Amphetamine Sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours" and "Lot No. 2974 * * * Formula: Del-Caps 15 mg."; (20,300-capsule lot) "Lot No. 2974 * * * Formula: Del-Caps 15 mg.," "Del-Caps Time Disintegration Capsules * * * Dextro amphetamine sulfate 10 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours," and "Del-Caps 15 Timed Disintegration Capsule * * * Dextro amphetamine sulfate 15 mg. * * * provides for the disintegration of the contents throughout a period of 6–10 hours."

RESULTS OF INVESTIGATION: Examination showed that the capsules in the 24,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 80 percent was released within 1 hour rather than uniformly over a 6- to 10-hour period; that the capsules in the 49,850-capsule lot contained 15 mg. per capsule of dextro-amphetamine sulfate, of which 81 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period; and that the 20,300-capsule lot contained 10 mg. per capsule of dextro-amphetamine sulfate, of which 90 to 99 percent was released within 2 hours rather than uniformly over a 6- to 10-hour period.

LIBELED: 1–3–58, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the quality of the article in all lots fell below that which it purported and was represented to possess since the capsules failed to disintegrate as indicated; 502(a)—the statement "Timed Disintegration Capsules * * * provides for the disintegration of the contents throughout a period of 6–10 hours" on the labels of the 49,850- and 20,300-capsule lots was false and misleading; 502(e)(2)—the label of the capsules in the 24,850-lot failed to bear the common or usual name of each active ingredient; and 503(b)(4)—the capsules in the 24,850-capsule lot were a drug subject to 503(b)(1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without a prescription."

DISPOSITION: 2–26–58. Default—destruction.